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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,728	08/10/2001	Peter Geistlich	1194-179	5552

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

TB

Office Action Summary	Application N .		Applicant(s)	
	09/925,728		GEISTLICH ET AL.	
	Examiner		Art Unit	
	Brian E Pellegrino		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 12, 15, 16, 18, 19, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (WO 95/18638) in view of Vibe-Hansen et al. (5759190). Geistlich et al. disclose a method of *promoting tissue regeneration* in a cavity or lesion area by placing a membrane over the area with the cell barrier layer facing away from the lesion, page 11, last paragraph. Geistlich additionally discloses the membrane has a smooth face or layer which acts as a barrier to cells and another layer which is fibrous and acts as a matrix for cells, page 2. Geistlich discloses that the matrix layer or fibrous side and barrier side is impregnated with a GAG or hyaluronic acid, page 8, third paragraph and page 10. Geistlich does disclose the collagen material can be treated or crosslinked to stabilize the membrane and reduce its resorption rate, page 7-8. Geistlich also discloses that taurolidine can be used with the membrane for chemotherapeutic purposes, page 11, lines 7-10. However, Geistlich et al. do not disclose the membrane being used in a cavity for cartilage *tissue regeneration* or the types of collagen in the membrane or how the membrane is secured to the area of use. Vibe-Hansen teaches that tissue regeneration of surface cartilage can be promoted by applying a collagen membrane patch charged with chondrocytes to a joint area, (col. 2, lines 17-34). Vibe-Hansen et al. also teach the collagen membrane matrix layer is collagen II, col. 8, lines 43-45. The patch is fixed over the area either by adhesively

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bonding or suturing the patch to cartilage surrounding the area treated, col. 7, lines 14-18. The patch has a barrier layer with a smooth or dense face and a fibrous or porous face with the matrix adhered thereto, col. 7, lines 57-67. Vibe-Hansen additionally discloses the membrane as having a barrier layer or dense surface made of collagen I and III taken from pigs, col. 7, lines 7-13. It would have been obvious to one of ordinary skill in the art to use a collagen II matrix membrane and attach it to a defective area of a cartilage joint as taught by Vibe-Hansen using the method of Geistlich in order to repair a cavity such as a cartilage joint needing tissue regeneration.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (WO 95/18638) in view of Vibe-Hansen et al. '190 as applied to claim 7 above, and further in view of Sonis (WO 90/13302). Geistlich as modified by Vibe-Hansen et al. is explained supra. However, Geistlich in view Vibe-Hansen do not disclose the membrane carrying pharmaceutically active substances, such as BMPs. Sonis teaches that BMPs can be used with membranes for tissue regeneration, page 10, lines 22-31. Table II (page 28) show numerous agents, i.e. PDGF or PTH. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with a pharmaceutically active substance as taught by Sonis in the membrane of Geistlich in view of Vibe-Hansen in order to enhance the capabilities of the tissue regeneration process and allow for controlled release of the substances.

Claims 10,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (WO 95/18638) in view of Vibe-Hansen et al. '190 as applied to claim 1 above, and further in view of Caplan et al. (5197985). Geistlich as modified by Vibe-

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Hansen et al. is explained supra. However, Geistlich in view Vibe-Hansen do not disclose the use of stem cells or stromal cells incorporated in the membrane. Caplan et al. teach that mesenchymal stem cells can be incorporated into carriers or membranes for tissue regeneration, col. 2, lines 6-11,27-34. Caplan also teaches that the stem cells are capable of determining which connective tissue to regenerate, i.e. cartilage, col. 3, lines 20-24,35-45. The cells and carrier is used to repair cartilage of a joint, col. 16, lines 40-53. Caplan additionally teaches that stromal cells from bone marrow can be harvested for use, col. 15, lines 25-28,39-49. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with stem or stromal cells as taught by Caplan et al. in the membrane of Geistlich as modified by Vibe-Hansen in order to provide enhanced osteogenic activity.

Claims 13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (WO 95/18638) in view of Vibe-Hansen et al. '190 as applied to claim 1 above, and further in view of Geistlich et al. (5573771). Geistlich (WO 95/18638) as modified by Vibe-Hansen et al. is explained supra. However, Geistlich (WO 95/18638) in view Vibe-Hansen do not disclose the use of a bone mineral implanted in the region of the bone injury. Geistlich et al. '771 teach that a bone mineral is useful for implanting in a bone cavity for remodeling, col. 2, lines 52-62. Geistlich '771 also teaches the bone mineral improves strength of the bone at the defect and these implants can be charged with bone cells, col. 3, lines 10-15,53-56. It would have been obvious to one of ordinary skill in the art to use a bone mineral as taught by Geistlich et al. '771 charged with the chondrocytes in the membrane of Geistlich (WO 95/18638) in view of Vibe-Hansen in

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order strengthen the area of the defect and provide a more natural environment for the cells.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (WO 95/18638) in view of Vibe-Hansen et al. '190 as applied to claim 1 above, and further in view of Seid (5254133). Geistlich as modified by Vibe-Hansen et al. is explained supra. However, Geistlich in view Vibe-Hansen do not disclose the use of two barrier layers to sandwich the matrix. Seid teaches (Fig. 13) that a coating **76** forms a barrier layer that sandwiches an inner component of the tissue patch. Seid also teaches the coating prevents tissue formation, col. 9, lines 3-8. It would have been obvious to one of ordinary skill in the art to use a barrier layer on both sides of the matrix of Geistlich as modified by Vibe-Hansen using the teaching of Seid to inhibit tissue formation prematurely.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (WO 95/18638) in view of Vibe-Hansen et al. '190 as applied to claim 1 above, and further in view of Stone et al. (5624463). Geistlich as modified by Vibe-Hansen et al. is explained supra. However, Geistlich in view Vibe-Hansen do not disclose the collagen II material is crosslinked. Stone et al. teach that the matrix layer is crosslinked and forms a covering for a cartilage defect, col. 3, lines 8,9,12-18,23,24. Stone also teaches that collagen II is a useful matrix material, col. 6, lines 3,4,12,13,36-39. The type II collagen is natural cartilage, col. 7, lines 53,54,62,63. The collagen II can be obtained from pigs, col. 8, lines 62,63. It would have been obvious to one of ordinary skill in the art to have a collagen II matrix that is crosslinked as taught by Stone et al. as

the matrix in the membrane of Geistlich in view of Vibe-Hansen et al. in order to strengthen the matrix.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738
7/10/03



Paul Prebilic

Primary Examiner